



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,741	11/30/2001	Mary M. Dyszlewski	1328 WO/US	2094

7590 06/15/2004
Jeffrey S Boone
Mallinckrodt Inc
675 McDonnell Boulevard
PO Box 5840
St Louis, MO 63134

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,741

Applicant(s)

DYSZLEWSKI ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,10-16,23-26,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7,10-16,23-26,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1616

ACKNOWLEDGMENTS

1. The Examiner acknowledges the acceptable RCE filed 4/5/04. In addition, the Examiner acknowledges the amendment filed 4/15/04 wherein the claim status is as follows: claims 6 and 15 amended and claims 1-5, 8, 9, 17-22, and 27 canceled.

Note: Claims 6, 7, 10-16, 23-26, 28, and 29 are pending.

RESPONSE TO APPLICANT'S AMENDMENTS

2. The Applicant's arguments filed 4/5/04 to the rejection of claims made by the Examiner under 35 USC 102 have been fully considered and deemed persuasive because Applicant has amended the claims to overcome the rejection. Thus, the said rejection is hereby withdrawn.

NEW GROUNDS OF REJECTION

112 First Paragraph Rejection (New Matter)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 6, 7, 10-16, 23-26, 28, and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

Art Unit: 1616

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, the claims have incorporated new matter because of the phrase 'non-aromatic aminopolycarboxylate multidentate' which is not set forth in the specification. For example, when the application was filed it is unclear that all non-aromatic aminopolycarboxylate multidentate ligands were envisioned. While it is noted that the specification discloses some non-aromatic aminopolycarboxylate multidentate ligands, DTPA, EDTA, DOTA, IDA, and NTA, the disclosure as originally filed and the claims as now amended are not consistent since the amended claims read on any and all non-aromatic aminopolycarboxylate ligands.

112 Second Paragraph Rejection

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6, 7, 10-16, 23-26, 28, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because of the phrase 'non-aromatic aminopolycarboxylate multidentate'. In particular, the phrase is confusing because it is not clear whether Applicant's phrase should be interpreted as the non-aromatic portion of the ligand is the portion that binds the metal or if the phrase should be interpreted as there is not an aromatic group in the entire aminopolycarboxylate structure.

Art Unit: 1616

Double Patenting Rejection

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 6, 7, 10-16, 23-26, 28, and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 9, 11, and 13-17 of U.S. Patent No. 6,359,119. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds having the formula $\text{fac}[\text{M}(\text{CO})_3\text{L}_x]^n$ wherein L_x is more than one bidentate (multidentate) ligand. The claims differ in that the patented invention

Art Unit: 1616

reads on various types of multidentate ligands (three monodentate ligands, one monodentate ligand and one bidentate ligand, and one tridentate ligand). Thus, it would have been obvious to a skilled practitioner in the art that the term 'multidentate' encompasses the various dentate ligands in the patent since the ligands together result in complexes having more than one (multidentate) ligand. In addition, while the patented claims do not specifically, state that the composition may be found in a kit having various components, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a kit because of the disclosure of the patented specification (column 2, lines 50-60; column 6, lines 24-55) and the ever present need for such kits in hospitals, clinics, or other medical facilities to aid in rapidly obtaining results regarding a subjects condition.

103 Rejection

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 6, 7, 10-16, 23-26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pipes et al (US Patent No. 6,359,119).

Pipes et al disclose the formulation of carbonyl complexes having the formula

Art Unit: 1616

$\text{fac}[\text{M}(\text{CO})_3\text{L}_x]^n$ wherein L_x is more than one bidentate ligand. Specifically, L_x is a mixture of multidentate ligands or a monodentate ligand (see entire document, especially, abstract). Possible metals which may be used in the formula include Mn, Tc, and Re (column 2, lines 32). In addition, Pipes et al disclose that reductants of borohydrides have been successful in the art with technetium complexes (column 2, lines 50-60). A kit may be generated for carrying out labeling reactions with the metal in a clinical hospital or laboratory. Various components such as a reducing agent, an inert carrier (i.e., lactose), metal, carbon monoxide, and tartrate may be present in the kit (column 6, lines 26-57; column 9, lines 46-53). Hence, both the instant invention and the cited prior art disclose carbonyl complexes, even though the claims differ in how they describe the dentate ligand.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a compound, method of preparing the compound, and a kit containing the compound having the limitations of independent claims 6 and 15 because Pipes et al disclose compounds, a kit, and a method of preparing the compound as set forth in Applicant's claims. The claims differ in that the patented invention reads on various types of multidentate ligands (three monodentate ligands, one monodentate ligand and one bidentate ligand, and one tridentate ligand). However, it would have been obvious to a skilled practitioner in the art that the term 'multidentate' encompasses the various dentate ligands in the patent since the ligands together result in complexes having more than one (multidentate) ligand. In addition, Pipes et al specifically state that the composition may be found in a kit having various components

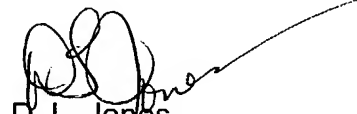
Art Unit: 1616

such as a reducing agent, borate, lactose, and so forth which are also present in the instant invention.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
Art Unit 1616

June 7, 2004